Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 August 2009 has been entered.

DETAILED ACTION

This Office Action is in response to Applicants' Remarks filed on 14 August 2009.

Claims 1-13 and 22-24 are pending in the instant application.

Claims 7, 8 and 10 were previously withdrawn from further consideration in the Office Action dated 24 October 2008 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 22 and 24 were previously withdrawn from further consideration in the Office Action dated 14 April 2009 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 1-6, 9, 11-13 and 23 will be examined on its merits herein.

Priority

This application is a National Stage entry of PCT/EP2005/000215 filed on 12 January 2005 and claims priority to Germany foreign application 10 2004 002 001.9

filed on 14 January 2004. A certified copy of the foreign priority document in German has been received. No English translation has been received.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Section [0001]

Claims 1-4, 6, 9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub No. US 2004/0136925 A1 to Petrigni *et al.* (PTO-892, Ref. A), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.* (herein referred to as the '224 patent, of record).

Petrigni *et al.* teach pharmaceutical preparations containing a suitable mixture, in colloidal form, of biopolymerized hyaluronic acids as the active ingredient, having defined and different molecular weights and being dispersed in suitable diluents, and their use in the treatment of pathological cutaneous diseases (paragraph 0001 and 0010). The pharmaceutical preparation in colloidal liquid form is preferably administered by topical route, but may also be conveniently administered through a general route, such as subcutaneous intramuscular intradermal infection, or in a solid form by oral route or as a transdermal plaster by transcutaneous route (paragraph 0012). The hyaluronic acids of the mixture have molecular weights ranging from 200 kDa to 4,000 kDa. Petrigni *et al.* further exemplified the treatment of *acne vulgaris* (paragraphs 0023-0027), contact eczema (paragraphs 0028-0032) and atopical eczema (paragraphs 0033-0042) using the disclosed pharmaceutical preparation.

Although Petrigni *et al.* specifically teach that the pharmaceutical preparation comprises biopolymerized hyaluronic acids, it appears from the disclosed preparation procedure (Example 1, paragraph 0015-0020) that the hyaluronic acids were not crosslinked and thus "biopolymerized hyaluronic acids" merely refers to the typical

polymeric form of hyaluronic acid. Therefore, the teachings of Petrigni *et al.* differ from that of the instantly claimed invention in that the hyaluronic acid is not present in crosslinked form.

The Sakurai '224 patent teaches that the hyaluronic acid typically administered to a subject is isolated and purified from a source and lacks the stringiness and viscoelasticity of hyaluronic acid typically found in the living body (column 1, lines 35-40). Moreover, hyaluronic acid is known to undergo enzymatic decomposition or non-enzymatic oxidation-reduction decomposition after being administered to a living body, especially at diseased sites (column 1, lines 41-44). Crosslinked hyaluronic acid, on the other hand, shows resistance to enzymatic decomposition or non-enzymatic oxidation-reduction decomposition (column 1, lines 54-59). Thus, crosslinked hyaluronic acid has a wide variety of medical and cosmetic uses (column 1, lines 61-63). The crosslinking index (percent of crosslinking) of the resultant crosslinked hyaluronic acid or salt thereof from a reaction, may be controlled by varying the molar ratio of the hyaluronic acid, or salt thereof, to the polyfunctional epoxy compound used for crosslinking (column 3, lines 3-6). The cosmetic containing crosslinked hyaluronic acid may be in the form of a cream, lotion, or hair cosmetic (column 4, lines 30-33). Example 8 illustrates the use of crosslinked hyaluronic acid on rabbits (column 10, lines 14-68).

The Sakurai '224 patent discloses crosslinked hyaluronic acid with varying degrees of crosslinking, as indicated by their crosslinking index. For example, crosslinked hyaluronic acids with a crosslinking index per 1000 repeating disaccharides in hyaluronic acid of 8.5, 7.5, 13 and 40 and disclosed in Examples 1-4, respectively.

Moreover, the Sakurai '224 patent teaches that the degree of crosslinking may be controlled by varying the molar ratio of the hyaluronic acid, or salt thereof, to the polyfunctional epoxy compound used for crosslinking (column 3, lines 3-6). Thus, it is considered that one of ordinary skill in the art would have the capabilities of adjusting their reaction to obtain a crosslinked hyaluronic acid with the desired percent of crosslinking.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Petrigni *et al.*, concerning a pharmaceutical composition comprising hyaluronic acids and its use in the treatment of pathological cutaneous diseases, such as eczema or *acne vulgaris*, with the teachings of the Sakurai '224 patent, regarding the enzymatic decomposition and non-enzymatic oxidation-reduction of hyaluronic acid after being administered to a living body and how crosslinked hyaluronic acid is resistant to such decomposition. One would have been motivated to combine the teachings and crosslink the hyaluronic acids in the composition disclosed in Petrigni *et al.*, in order to receive the expected benefit, as suggested in the Sakurai '224 patent, that crosslinked hyaluronic acid shows resistance to enzymatic decomposition or non-enzymatic oxidation-reduction decomposition (column 1, lines 54-59). Thus, one of ordinary skill in the art would know that the compound's half-life would be increased as it is no longer subjected to enzymatic and non-enzymatic oxidation-reduction decomposition, which one of ordinary skill in the art would generally view as a positive pharmacokinetic property of drugs.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Section [0002]

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub No. US 2004/0136925 A1 to Petrigni *et al.* (PTO-892, Ref. A), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.* (herein referred to as the '224 patent, of record), as applied to claims 1-4, 6, 9 and 11-13, further in view of chapter publication by Wilkinson (of record).

The teachings of Petrigni *et al.* and the Sakurai '224 patent were as disclosed in section [0001] of the claim rejections under 35 USC § 103.

The combined teachings of Petrigni *et al.* and the Sakurai '224 patent differ from that of the instant invention in that they do not teach a method of treating inflammatory skin conditions wherein the composition comprises hyaluronic acid in both crosslinked and uncrosslinked form.

Wilkinson teaches the physiochemical factors involved in the transfer of drugs across membranes. Figure 1-6 discloses the therapeutic window in which a drug shows effectiveness (p. 25, first column). This window varies depending on factors such as the dosage, toxicity, absorption, distribution and its elimination half-life (p. 25, first column, first incomplete paragraph; p. 26, second column, first incomplete paragraph). In most clinical situations, drugs are administered in a series of repetitive doses or as a continuous infusion so as to maintain a steady-state concentration of drug associated

with the therapeutic window (p. 26, first column, subheading "Maintenance Dose", first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Petrigni *et al.*, concerning a pharmaceutical composition comprising hyaluronic acids and its use in the treatment of pathological cutaneous diseases, such as eczema or *acne vulgaris*, with the teachings of the Sakurai '224 patent, regarding the enzymatic decomposition and non-enzymatic oxidation-reduction of hyaluronic acid after being administered to a living body and how crosslinked hyaluronic acid is resistant to such decomposition, with the teachings of Wilkinson, regarding the therapeutic window of a drug and how it varies according to the drug's absorption, distribution and elimination characteristics. Since Petrigni *et al.* teach the treatment of pathological cutaneous diseases, such as eczema or *acne vulgaris* by administrating a composition comprising hyaluronic acids, and the Sakurai '224 patent teaches that crosslinked hyaluronic acid is resistant to enzymatic and chemical degradation, as well as the use of crosslinked hyaluronic acid, one would have been motivated to combine the teachings to make a composition comprising hyaluronic acid in both crosslinked and uncrosslinked form, in order to receive the expected benefit, that the combined composition would increase the therapeutic window of the drug. Based on the teachings of Wilkinson and the knowledge of one or ordinary skill in the art, one would know that the uncrosslinked compound likely takes effect faster, but is also degraded faster, while crosslinked hyaluronic acid would remain in the bloodstream longer, thereby increasing the therapeutic window of effectiveness of the drug.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Section [0003]

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over PG Pub No. US 2004/0136925 A1 to Petrigni *et al.* (PTO-892, Ref. A), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.* (herein referred to as the '224 patent, of record), as applied to claims 1-4, 6, 9 and 11-13, further in view of journal publication by Sterling *et al.* (PTO-892, Ref. U).

The teachings of Petrigni *et al.* and the Sakurai '224 patent were as disclosed in section [0001] of the claim rejections under 35 USC § 103.

The combined teachings of Petrigni *et al.* and the Sakurai '224 patent differ from that of the instant invention in that they do not teach a pathological cutaneous disease which is a viral skin disease leading to wart formation.

Sterling *et al.* teach that cutaneous warts are caused by the infection of the epidermis with human papillomarvirus (HPV) (p. 4, column 1, subheading "Definition," first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Petrigni *et al.*, concerning a pharmaceutical composition comprising hyaluronic acids and its use in the treatment of pathological cutaneous diseases, such as eczema or *acne vulgaris*, with the teachings of the Sakurai '224 patent, regarding the enzymatic decomposition and non-enzymatic oxidation-

reduction of hyaluronic acid after being administered to a living body and how crosslinked hyaluronic acid is resistant to such decomposition, with the teachings of Sterling *et al.*, regarding cutaneous warts being caused by HPV. Since Sterling *et al.* teach that warts are a pathological cutaneous disease and Petrigni *et al.* teach that the disclosed composition comprising hyaluronic acid can be administered in the treatment of pathological cutaneous diseases, one would have been motivated to combined the teachings and administer the composition comprising hyaluronic acid to a patient with warts, with the expectation that since warts are a pathological cutaneous disease, the composition comprising hyaluronic acid would also be successful in the treatment of warts. One would have been further motivated to combine the teachings and crosslink the hyaluronic acids in the composition disclosed in Petrigni *et al.*, in order to receive the expected benefit, as suggested in the Sakurai '224 patent, that crosslinked hyaluronic acid shows resistance to enzymatic decomposition or non-enzymatic oxidation-reduction decomposition (column 1, lines 54-59), as disclosed above.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

The following rejections of record in the previous Office Action are maintained.

Section [0004]

Claims 1-4, 9, 11-13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,914,322 to Falk *et al.* (herein referred to as the '322 patent, of record), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.* (herein referred to as the '224 patent, of record), in view of U.S. Patent No. 6,455,066 B1 to Fischer *et al.* (herein referred to as the '066 patent, of record).

The Falk '322 patent discloses that a therapeutically effective amount of hyaluronic acid in a composition is useful in the treatment of skin diseases and conditions by topically administering said composition to a subject. The topical composition may be used to treat diseases and conditions of the skin such as genital warts cervical cancer, human papilloma virus (HPV), and psoriasis, among others (column 7, lines 10-22; column 12, lines 28-39). The composition may be in any suitable form, such as a lotion or a cream (column 8, lines 61-62). As shown in Formulation (A), the weight of sodium hyaluronate is 661,600 (661 kDa) (column 13, lines 10-23). Examples 1-7 illustrate the use of the composition on human patients with lesions (Examples 1-3) or psoriasis (Example 7) (columns 25 and 26).

The Falk '322 patent does not explicitly teach that hyaluronic acid is in the crosslinked form or that it is administered intradermally.

The Sakurai '224 patent teaches that the hyaluronic acid typically administered to a subject is isolated and purified from a source and lacks the stringiness and viscoelasticity of hyaluronic acid typically found in the living body (column 1, lines 35-40). Moreover, hyaluronic acid is known to undergo enzymatic decomposition or non-enzymatic oxidation-reduction decomposition after being administered to a living body,

especially at diseased sites (column 1, lines 41-44). Crosslinked hyaluronic acid, on the other hand, shows resistance to enzymatic decomposition or non-enzymatic oxidation-reduction decomposition (column 1, lines 54-59). Thus, crosslinked hyaluronic acid has a wide variety of medical and cosmetic uses (column 1, lines 61-63). The crosslinking index (percent of crosslinking) of the resultant crosslinked hyaluronic acid or salt thereof from a reaction, may be controlled by varying the molar ratio of the hyaluronic acid, or salt thereof, to the polyfunctional epoxy compound used for crosslinking (column 3, lines 3-6). The crosslinked hyaluronic acid may be used in skin cosmetics (column 4, lines 4-6), for application on, for example, shaving, cracking, and chappy skin (column 4, lines 28-30). The cosmetic containing crosslinked hyaluronic acid may be in the form of a cream, lotion, or hair cosmetic (column 4, lines 30-33). Example 8 illustrates the use of crosslinked hyaluronic acid on rabbits (column 10, lines 14-68).

The Sakurai '224 patent discloses crosslinked hyaluronic acid with varying degrees of crosslinking, as indicated by their crosslinking index. For example, crosslinked hyaluronic acids with a crosslinking index per 1000 repeating disaccharides in hyaluronic acid of 8.5, 7.5, 13 and 40 and disclosed in Examples 1-4, respectively. Moreover, the Sakurai '224 patent teaches that the degree of crosslinking may be controlled by varying the molar ratio of the hyaluronic acid, or salt thereof, to the polyfunctional epoxy compound used for crosslinking (column 3, lines 3-6). Thus, it is considered that one of ordinary skill in the art would have the capabilities of adjusting their reaction to obtain a crosslinked hyaluronic acid with the desired percent of crosslinking.

The Fischer '006 patent provides the general teaching that drug administration via the skin is divided into two categories: 1) transdermal administration and 2) intradermal administration (column 1, lines 39-41). Transdermal administration involves transport through the skin and into the blood stream to treat systemic diseases (column 1, lines 41-43). On the other hand, intradermal administration is intended to impart a cutaneous effect, while keeping the pharmacological effects of the drug localized to the intracutaneous regions of drug penetration and deposition (column 1, lines 43-47). Ideally, intradermal absorption occurs with little or no systemic absorption or accumulation.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Falk '322 patent, concerning the treatment of skin diseases and conditions by administering a composition comprising a therapeutically effective amount of a non-toxic drug that inhibits prostaglandin synthesis with a therapeutically effective amount of hyaluronic acid, with the teachings of the Sakurai '224 patent, regarding the enzymatic decomposition and non-enzymatic oxidation-reduction of hyaluronic acid after being administered to a living body and how crosslinked hyaluronic acid is resistant to such decomposition, with the teachings of the Fischer '006 patent, regarding the two routes for administering a drug to the skin, either transdermal or intradermal. One would have been motivated to combine the teachings in order to receive the expected benefit, as suggested in the Sakurai '224 patent, that crosslinked hyaluronic acid shows resistance to enzymatic decomposition or non-enzymatic oxidation-reduction decomposition (column 1, lines 54-59). Thus, one of

ordinary skill in the art would know that the compound's half-life would be increased as it is no longer subjected to enzymatic and non-enzymatic oxidation-reduction decomposition. With regards to the route of administration, one of ordinary skill in the art would have been motivated to combine the teachings in order to receive the expected benefit, as suggested in the Fischer '006 patent, that intradermal administration imparts a cutaneous effect, while keeping the pharmacological effects of the drug localized to the intracutaneous regions of drug penetration and deposition, which ideally results in little or no systemic absorption or accumulation. Furthermore, as one of ordinary skill in the art is aware that the absorption, distribution, metabolism and excretion of a drug is critically influenced by its route of administration, it is considered within the capabilities of one of ordinary skill in the art to determine the best route of administration for a drug to achieve optimal treatment results.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Section [0005]

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,914,322 to Falk *et al.* (herein referred to as the '322 patent, of record), in view of U.S. Patent No. 4,716,224 to Sakurai *et al.* (herein referred to as the '224 patent, of record), in view of U.S. Patent No. 6,455,066 B1 to Fischer *et al.* (herein referred to as the '066 patent, or record), as applied to claims 1-4, 9, 11-13 and 23, and further in view of chapter publication by Wilkinson (of record).

The teachings of the Falk '322 patent, the Sakurai '224 patent, and the Fischer '006 patent were as disclosed above in section [0001] of the claim rejections under 35 USC § 103.

The references do not teach a method wherein the composition comprises hyaluronic acid in both crosslinked and uncrosslinked form.

Wilkinson teaches the physiochemical factors involved in the transfer of drugs across membranes. Figure 1-6 discloses the therapeutic window in which a drug shows effectiveness (p. 25, first column). This window varies depending on factors such as the dosage, toxicity, absorption, distribution and its elimination half-life (p. 25, first column, first incomplete paragraph; p. 26, second column, first incomplete paragraph). In most clinical situations, drugs are administered in a series of repetitive doses or as a continuous infusion so as to maintain a steady-state concentration of drug associated with the therapeutic window (p. 26, first column, subheading "Maintenance Dose", first paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the Falk '322 patent, concerning the treatment of skin diseases and conditions by administering a composition comprising a therapeutically effective amount of a non-toxic drug that inhibits prostaglandin synthesis with a therapeutically effective amount of hyaluronic acid, with the teachings of the Sakurai '224 patent, regarding the enzymatic decomposition and non-enzymatic oxidation-reduction of hyaluronic acid after being administered to a living body and how crosslinked hyaluronic acid is resistant to such decomposition, with the teachings of the

Fischer '006 patent, regarding the two routes for administering a drug to the skin, either transdermal or intradermal, with the teachings of Wilkinson, regarding the therapeutic window of a drug and how it varies according to the drug's absorption, distribution and elimination characteristics. Since the Falk '322 patent teaches the treatment of skin diseases and conditions by administering a prostagladin synthesis inhibitor along with hyaluronic acid and the Sakurai '224 patent teaches that crosslinked hyaluronic acid is resistant to enzymatic and chemical degradation, as well as the use of crosslinked hyaluronic acid, then one would have been motivated to combine the teachings to make a composition comprising hyaluronic acid in both crosslinked and uncrosslinked form, in order to receive the expected benefit, that the combined composition would increase the therapeutic window of the drug. One of ordinary skill in the art would know that the uncrosslinked compound likely takes effect faster, but is also degraded faster, while crosslinked hyaluronic acid would remain in the bloodstream longer, thereby increasing the therapeutic window of effectiveness of the drug.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

Applicants' arguments filed 14 August 2009 with respect to the rejection of claims 1-4, 9, 11-13 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,914,322 to Falk *et al.*, in view of U.S. Patent No. 4,716,224 to Sakurai *et al.*, in view of

U.S. Patent No. 6,455,066 B1 to Fischer *et al.*, have been fully considered but they are not persuasive.

Applicants argue that since the Falk '322 patent teaches that the disclosed topical administration is the best administration route, there is no reason for one of ordinary skill in the art to alter the disclosed best route of administration to anything else. Additionally, Applicants argue that there is nothing in the general teaching of the Fischer '066 patent that would provide motivation for one to choose a particular route of administration over another. Applicants also argue that the Fischer '066 patent is silent with regards to the administration of any particular compound, e.g. hyaluronic acid. These arguments are not persuasive because the recitation from the Falk '322 patent cited by Applicants, "best targeting the epidermis and subsequently remaining there for a prolonged period of time," can also be interpreted as the disclosed method being better at targeting the epidermis as compared to any other part of the body, and not necessarily that the is the best method for targeting the epidermis, as interpreted by Applicants. In light of the former interpretation, the teaching of the Fischer '066 patent that "intradermal absorption occurs with little or no systemic absorption or accumulation," also cited by Applicants, would motivate one to choose the intradermal method of administration over trandermal or topical. With regards to the argument that the Fischer '066 patent is silent with regards to administration of hyaluronic acid, Applicants are requested to note that the reference is used in combination with other references, and thus the Fischer '066 patent need not teach administration of hyaluronic acid so long as the combined teachings of the prior art disclose administration of

hyaluronic acid. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, Applicants argue that the combined teachings of the Falk '322 patent, the Sakurai '224 patent, and the Fischer '066 patent leads away from the subject matter of the present application because the Falk '322 patent does not disclose hyaluronic acid as an active ingredient, but merely as a penetration agent for allowing an inhibitor of prostaglandin synthesis to penetrate the skin, and the Fischer '066 patent does not teach intradermal application of drugs, but rather, topical application of a combination of the drug in question and a penetration agent. This argument is not persuasive because although the Falk '322 patent does not disclose hyaluronic acid as the active ingredient, the properties of the compound are the same and would thus have the same effect, regardless of whether hyaluronic acid is intended to be used as the active ingredient or as a penetration enhancer, particularly since the targeted patient population, those with various skin conditions, are deemed to be the same or overlap. Furthermore, as the Fischer '006 patent teaches intradermal administration of a penetration enhancer to increase absorption of the topical drug, and as Applicants indicated, the Falk '322 patent teaches hyaluronic acid as a penetration enhancer, one would have been motivated to intradermally administer hyaluronic acid so as to increase the absorption of a topical administration of an inhibitor of prostaglandin synthesis. One would have been motivated to administer hyaluronic acid intradermally, rather than topically, as a penetration enhancer, in order to receive the expected benefit, as taught by the Fischer '006 patent, that intradermal absorption occurs with little or no systemic

absorption or accumulation. As mentioned earlier, regardless of whether hyaluronic acid is administered for the purpose of being a penetration enhancer or as an active ingredient, since the patient population is the same or overlaps, hyaluronic acid would also necessarily treat an inflammatory skin condition, such as warts.

The rejection is still deemed proper and therefore adhered to.

Applicants' arguments filed 14 August 2009 with respect to the rejection of claims 5 and 6 made under 35 USC § 103(a) as being unpatentable over U.S. Patent No. 5,914,322 to Falk *et al.*, in view of U.S. Patent No. 4,716,224 to Sakurai *et al.*, in view of U.S. Patent No. 6,455,066 B1 to Fischer *et al.*, as applied to claims 1-4, 9, 11-13, further in view of Wilkinson, have been fully considered but they are not persuasive.

Applicants argue that Wilkinson does not cure the deficiencies of the primary references. This argument is not persuasive for reasons as indicated above regarding the primary references. Thus, Wilkinson is properly used as a prior art for rejection of claims 5 and 6 in view of the primary references.

The rejection is still deemed proper and therefore adhered to.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-

270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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